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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,597	05/22/2000	John J. Voorhees	1718-009A	1700

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Hopgood Calimafde Kalil & Judlowe LLP
60 East 42nd Street
New York, NY 10165

EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/576,597	Applicant(s) VOORHEES ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-21* is/are pending in the application.

4a) Of the above claim(s) *10-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-9 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of application

1. Election of group I, claims 1, 3-9, 18-19 and 21 without traverse, has been acknowledged. Amendment has been also entered properly. Because of the recent amendment filed Nov. 21, 2001, the claims 18-19 should be excluded from the elected group I due to the dependency change, the claims 18-19, thus, will be included in Group III and will be withdrawn from consideration. The non-elected inventions, the claims 10-19 and 20 will be withdrawn from the consideration.

Response to Arguments

1. Applicant's arguments and Declaration under rule 1.132 filed September 17, 2001 have been fully considered but they are not persuasive. In response to applicant's arguments with respect to claims 1, 3-9 will not be included because the arguments are moot in view of the new ground(s) of rejection because the claims has been amended with the scope change.

2. Applicant's amendment with respect to claims 1, 3-9, 18-19 and 21 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

3. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-9 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Applicant fails reasonably provide best mode for recognizing or differentiating non-antioxidant MMP inhibitors from antioxidant MMP inhibitors. For instance, the instant disclosure only exemplifies few compounds as antioxidant in page 11, lines 5-20. Without the undue experiment, one skilled artisan would not know which MMP inhibitors among all the compounds have defined as antioxidant.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-9 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The claims are now amended to exclude antioxidant MMP inhibitors. However it is not clear whether applicant is excluding antioxidant MMP inhibitors as defined in page 11, lines 5-20. For instance, proanthocyanidine(elastase inhibitor, page 13, line 28) is known as antioxidant in the art(as evidenced by Murad US5962517, column 7, line59), but applicant uses it as elastase inhibitor, and not listed as an antioxidant MMP inhibitor in the instant disclosure. Thus it is not clear what to include or not, and how one would know and distinguish non-antioxidant MMP inhibitors from antioxidant MMP inhibitors. If applicant intended to use conventional wisdom, it is too much burden to the examiner to find which MMP inhibitors among all the compounds have defined as antioxidant.

Thus, clairification is required.

9. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-7 recite the limitation "antibacterial" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Thus the claims are properly rejected.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeligs (US 6,096,706).

The claims read on a composition comprising a non-retinoid, non-antioxidant inhibitor of a dermal matrix-degrading enzyme, selected from AP-1 inhibitors, NF-kB inhibitors, elastase inhibitors, adhesion antagonists and mixtures thereof; and an active ingredient selected from comedolytics, anti-inflammatories, retinoids, glucocorticoids, and compatible mixtures thereof. Claim 9 requires an antioxidant in addition to the said composition.

Zeligs teaches a composition comprising dehydroepiandrosterone(DHEA) and retinoid. It also teaches additives such as vitamin C(ascorbic acid); see claims 1 and 12. It further teaches various application such as topical, oral, intravenous and sublingual administration see claims 5-20 and claim 56.

Applicant's claims differ because they required ap-1 inhibitor. However, as applicant has admitted in the instant disclosure, DHEA is well known in the art as an AP-1 inhibitor; see instant disclosure, page 12, lines 28-31, applicant cited " Dashtaki et al....".

Thus, it would have been obvious to substitute Zelig's patented composition in the place of Applicant's claimed composition for the same intended use. One would have expected success of the substitution. Thus the claimed subject matter is prima facie obvious over the prior art of the record. The selection of optimal dosages and formulations in order to determine the most effective treatment and to satisfy patient's preference is well within the skilled level of one having ordinary skill in the art, and is obvious.

All the claimed subject matters are not patentably distinct and properly included in this rejection.

Claims 6-7 are included in this rejection because the further limitation is not valid as set forth in 112 rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanzendorfer et al(US 6,180,662).

Lanzendorfer et al also teaches a composition useful in the treatment of acne, comprising (a) cinnamic acid(e.g. caffeic acid); (b) cyclosporine A; and (f) antimicrobial; see abstract and exemplified combinations-column 14-16 and column 11, lines 12-15000000.

Applicant's claims may differ because they require specific terms such as "neutrophil elastase inhibitors" or "MMP inhibitors".

For instance, elastase inhibitor, caffeic acid taught in the instant disclosure (page 13, lines 28) and is the species required by the instant claims. Applicant also admitted that cyclosporine A is AP-1 inhibitor which is also MMP inhibitors.

Therefore it would have been obvious to select caffeic acid, cyclosporine A and antimicrobial agent to make a effective composition as suggested by the cited reference to substitute the claimed composition wherein all these compounds inherently possess the claimed features(e.g. Ap-1 inhibitor, MMP inhibitor, etc). One would have been motivated to make such modification and substitution, with reasonable expectation of success, because it is advantageous to use the product wherein the safety and effectiveness is proven, especially for the same intended use.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

Conclusion

All the elected claims 1, 3-9 and 21 are rejected.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
November 29, 2001

William Jarvis
Primary examiner
Art unit 1614